Endoscopic Treatment of Anastomotic Esophageal Stricture. A Randomised Study Comparing Initial Dilation by Electrocautery with Savary Bougies with Electrocautery.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23356

Bron
Nationaal Trial Register

Verkorte titel
Endoscopic Treatment of Anastomotic Esophageal Stricture. A Randomised Study Comparing Initial Dilation by Electrocautery with Savary Bougies with Electrocautery.

Aandoening

English:Anastomotic Esophageal Stricture, Randomised Study, Electrocautery, Savary Bougies, dilatation.
Nederlands: stenose anastomose oesophagus, elektrocoagulatie, Savary Bougies, Gerandomiseerde studie

Ondersteuning

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Overige ondersteuning: Non

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

This study aims to compare the efficacy of Savary dilation versus endoscopic electrocautery treatment for the treatment of fibrotic anastomotic strictures after esophageal resection. The efficacy of therapy will be evaluated by means of objective and subjective criteria which will be determined both before treatment and during follow-up after treatment.
The objective criteria are obtained by standard items at endoscopy and body weight. Endoscopic evaluation of the stricture will take place at baseline, and will be repeated in case of recurrent or persistent symptoms.
The EORTC health related Quality of Life Questionnaires SF-36, C-30 (version 3) and OES 18 are used to structure a quality of life questionnaire especially focused on benign esophageal stenosis.

Toelichting onderzoek

Achtergrond van het onderzoek

Summary:

Anastomotic strictures are common after esophageal resection. These strictures often need multiple dilation procedures with Savary bougies, and some even fail despite many dilations. Based on the literature and our pilot study of electrocautery therapy of refractory benign esophageal stenosis (Hordijk Marjan L. , Siersema Peter D., Tilanus Hugo W. , Kuipers Ernst J. Electrocautery therapy for refractory anastomotic strictures of the esophagus. Gastrointest Endosc 2006;63:157-63.), electrocautery treatment is safe, and may provide an excellent alternative for primary treatment of esophageal strictures. A prospective randomized

controlled is needed to compare dilation therapy with Savary bouginage with electrocautery therapy for the primary treatment of these strictures.

Doel van het onderzoek

Anastomotic strictures are common after esophageal resection. These strictures often need multiple dilation procedures with Savary bougies, and some even fail despite many dilations. Based on the literature and our pilot study of electrocautery therapy of refractory benign esophageal stenosis (Hordijk Marjan L. , Siersema Peter D., Tilanus Hugo W. , Kuipers Ernst J. Electrocautery therapy for refractory anastomotic strictures of the esophagus. Gastrointest Endosc 2006;63:157-63.), electrocautery treatment is safe, and may provide an excellent alternative for primary treatment of esophageal strictures.
A prospective randomized controlled is needed to compare dilation therapy with Savary bouginage with electrocautery therapy for the primary treatment of these strictures.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

- Upper gastrointestinal endoscopy will be performed. The postoperative stenosis will be inspected and the diameter of the stenosis will be estimated by using the diameter of the endoscope (9.5 mm). These stenoses are usually located at 17 to 20 cm from the incisors.

- For endoscopic bougie dilation of the stricture, a guide wire will be placed in the stomach, followed by removal of the endoscope and passage of Savary Gilliard bougies (Wilson Cook) of increasing diameter over the guidewire according to standard procedures to a diameter of minimal of 16 mm and maximal 19 mm.

- For endoscopic dilation of the strictures with electrocautery, the tip of the endoscope is positioned just proximal from the stenosis, and a needle knife catheter (Wilson Cook, Boston Scientific) is introduced through the working channel. Radial incisions are made in the stenotic ring with the needle knife catheter under direct visualization. The required length of the cut is gauged according to the length of the stricture assumed by the endoscopist in the light of the membranous nature and the caliber of the stricture. The depth of the incision (estimated using the length of the needle knife as a comparator) is not deeper than 4 mm. The length of the incision is dosed to completely remove the rim of the stenosis.

- In case of recurrent stenosis, dilation therapy will be repeated with the same modality as was used at baseline. Recurrent stenosis is defined as no passage or only passage with pressure of the endoscope (diameter 9.5 mm.).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Sixty-two unselected consecutive patients with dysphagia due to a benign anastomotic stricture after transhiatal oesophagectomy with gastric tube reconstruction and cervical anastomosis will be included and randomized to either treatment arm. After informed consent, patients will either undergo dilation with Savary bougies, or primary electocautery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Esophageal dilation with bougies or electrocautery is rarely contraindicated.
Patients should however not be dilated if they recently suffered from acute esophageal perforation.

2. Dilation is relatively contraindicated in the presence of:

a. a bleeding diathesis,

b. severely compromised pulmonary function,

c. severe or unstable cardiac disease, or in

d. patients with large thoracic aortic aneurysms (47).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-06-2004
Aantal proefpersonen:	62
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-03-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL906
NTR-old	NTR931
Ander register	: N/A
ISRCTN	ISRCTN81239664

Resultaten